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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,487	01/07/2002	Spiros Fotinos	366325-509	3570

25561 7590 02/08/2006

JOHN W. RYAN  
C/O DECHERT LLP  
PRINCETON PIKE CORPORATION CENTER  
P.O. BOX 5218  
PRINCETON, NJ 08543-5218

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/036,487	<b>Applicant(s)</b> FOTINOS ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 24-45 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks, all filed 11/21/05 and request for extension of time filed 11/21/05 and 4/25/05. Claims 24 to 45 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 11/21/05 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 41 recites the limitation "0.01 to 15 wt% permeation enhancer" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 24 does not have

Art Unit: 1618

“permeation enhancer” in the uniform layer. It appears that the uniform layer further comprises “permeation enhancer.”

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 24-34, 36-40 and 43-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Biederman et al. (US 5,980,921).

Biederman discloses topical composition comprising effective amount of active agent in a more preferred amount of about 0.1% to about 10% and cosmetically acceptable topical carrier such as propylene glycol and polyethylene glycol (column 2, lines 42-46; column 3, lines 19-21; column 4, lines 38-43; column 5, lines 4-16). The composition of Biederman is formulated as a cleansing composition in the form of bath gels, liquid, shampoos, hair tonic, pastes and mousses; the composition comprises surfactants such as sodium lauryl sulfate in a preferred amount of from about 5% to about 10% (column 6, lines 17-28 and 39-46); the composition comprises film forming polymer that is not tacky (column 8, lines 56-67) and polyvinyl pyrrolidone is one of the preferred polymers and is present in amounts of 0.5 wt% to 10 wt% (column 9, lines 37, 43); the composition further comprises plasticizers such as glycols and glycerols, which are present in amounts of about 0.5% to 30% (column 10, lines 12-38); it is specifically disclosed that the

Art Unit: 1618

preferred polymer and the plasticizing solvent (plasticizer) are chosen such that the polymer and the plasticizing solvent are in the aqueous phase of the emulsion which reduces tacky sensation of the polymer on the users hands during application (column 10, lines 39-46). Niacinamide, pyridoxine, panthenol, pantothenic and mixtures thereof are the primary actives (column 4, lines 21-28). In addition to the primary actives, the composition of Biederman optionally contains other active agents namely: anti-inflammatory agents, retinoids, antimicrobial agents, antiandrogens, sunscreens, sunblocks, anti-oxidants/radical scavengers, chelators, hydroxyl acids such as salicylic acid and lactic acid, desquamation agents, depilation agents and skin lightening agents (columns 11-16). Salicylic acid, lactic acid and retinoids are anti acne agents. The glycols meet the limitations of claim 30. Polyvinylpyrrolidone meets the limitation of claims 1, 31-34. Antimicrobials meet the limitations of claim 29. Lauryl sulfate meets the limitation of claim 36. Propylene glycol and lauryl sulfate meet the limitation of permeation enhancer. As a cleansing product, the composition of Biederman meets the limitations of claims 43-45.

The comprising language of the claims is open and does not exclude other components present in the composition of Biederman and thus meets the limitations of the claims.

The examined application is a CIP of 09/340,338 and may not enjoy filing date of the parent 09/340,338.

7. The rejection of claims 1-4, 6-8, 20-22 under 35 U.S.C. 102(b) as being anticipated by Lorenz et al. (US 5,420,197) is withdrawn in light of the cancellation of the claims.

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1618

9. Claims 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biederman et al. (US 5,980,921).

Biederman is discussed above and discloses the film forming composition of the claimed invention. Biederman does not disclose a single layer device. Regarding claim 35, there is no demonstration that at least 75% of the film-forming polymer provides unusual/unexpected results to the composition. The cleansing formulation is applied to the skin and the application may be in a single layer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the composition of Biederman to the skin as a cleansing composition. One having ordinary skill in the art would have been motivated to apply the composition to the skin in a single layer with the expectation of uniform/efficient cleaning.

10. The rejection of claims 10-19 under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al. (US 5,420,197) is withdrawn in light of the cancellation of the claims.

### ***Response to Arguments***

Applicants' arguments with respect to Lorenz as it applies to the new claims have been considered and the arguments are found persuasive.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

Art Unit: 1618

USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 24, 25, 30-32, 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67 and 71-75 of copending Application No. 09/340,338. Although the conflicting claims are not identical, they are not patentably distinct from each other because future intended use recited in co-pending claim 67 carries no patentable weight in a composition/device claim, the amount of the polyvinyl pyrrolidone can be optimized to provide desired film over the skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.